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5 510(k) Summary

Non-Confidential Summary of Safety and Effectiveness
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Official Contact: Stephan Ploquin, Quality Manager, Regulatory Affairs

Proprietary or Trade Name: 4DDome®

Common/Usual Name: Polymeric Surgical Mesh

Classification Name: Polymeric Surgical Mesh

Predicate Devices: WL Gore – Bio-Absorbable® Hernia plug – K033671
Bard – Perfix® plug mesh – K922916
Atrium – Atrium® self forming plug – K930669

Device Description:

The 4DDOME® device is composed of a dome and onlay patch. The dome is made of 10 % light polypropylene and 90 % resorbable Poly-L-Lactide (PLLA). The dimensional stability of the dome combined with the physiological absorption of the PLLA ensure that the hernia sac is kept in place and the transversalis fascia is strengthened due to the PLLA generating cellular fibrosis.

The 4DDOME® medical device is composed of two prosthesis:

- one semi-resorbable dome
- one semi-resorbable onlay patch

The dome is the architectural structure with the best resistance to pressure. It keeps the hernia sac in the preperitoneal space behind the transversalis fascia by supporting itself on the sides of the defected area, where it is fixed with non-resorbable threads.

Indicated Use: 4DDome® is a semi-resorbable surgical plug and mesh for abdominal reinforcement, including open surgical repair and reinforcement of iguinal and crural hernias.

Contraindications: Do not implant in the following cases:
Allergy to one of components
Septic environment
Pregnancy
Growing children

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Device Attributes:

Type of product	**DOME**	**DOME**	**DOME**
Reference	4DDOME24SR	4DDOME30SR	4DDOME38SR
Size	Small (Diameter 24 mm)	Large (Diameter 30 mm)	Extra Large (Diameter 38 mm)
Material	88.3 % PLLA 11.7 % Polypropylene	88.3 % PLLA 11.7 % Polypropylene	88.3 % PLLA 11.7 % Polypropylene
Weight/m^2 (gm/m^2)	256	256	256
Macropores percentage (%)	74	74	74
Thickness (mm)	0.8 to 1	0.8 to 1	0.8 to 1
Weight per dome (gm)	0.2873	0.4573	0.6811
Weight of the dome after absorption (gm)	0.035	0.054	0.080

Physical properties of Dome component

Type of product	**Onlay patch**
Material	75 % PLLA monofilament 25 % polypropylene monofilament
Weight/m^2 (gm/m^2)	116
Structure	Knitwear semi-resorbable
Dimensions	Mesh 90 x 52 mm
Thickness (mm)	0.8

Physical properties of the semi-resorbable onlay patch:

Differences Between Other Legally Marketed Predicate Devices

The 4DDome® is viewed as substantially equivalent to the following predicate device – WL Gore – Bio-Absorbable® Hernia plug – K033671,Bard – Perfix® plug mesh – K922916, and Atrium – Atrium® self forming plug – K930669

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cousin Biotech
% ProMedic, Inc.
Mr. Paul Dryden
Regulatory Consultant
3460 Pointe Creek Court, #102
Bonita Springs, Florida 34134-2015

AUG 2 2 2007

Re: K070918
Trade/Device Name: 4DDome®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 2, 2007
Received: August 6, 2007

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

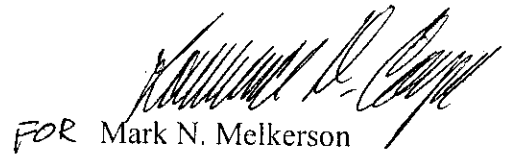
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



FOR Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Indications for Use Statement

510(k) Number: K070918 (To be assigned)

Device Name: 4DDome®

Indications for Use: 4DDome® is a semi-resorbable surgical plug and mesh for abdominal reinforcement, including open surgical repair and reinforcement of iguinal and crural hernias.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070918